

REMARKS

Status of the Claims

Claims 16, 18, 31, 34, 36 and 38-45 are currently pending in the application. Claims 16, 18, 21-23, 31, 32, 34 and 36-38 stand rejected. Claims 16 and 18 have been amended as set forth herein. Claims 21-23, 32 and 37 have been cancelled herein. All amendments and cancellations are made without prejudice or disclaimer. New claims 39-45 have been added herein. No new matter has been added by way of the present amendments.

Specifically, the amendment to claim 16 is supported throughout the specification, for instance, at page 4, lines 1-10.

The amendment to claim 18 is supported throughout the specification at, for instance, page 4, lines 5-7 and claim 19.

New claim 39 is supported by the claims and throughout the entire specification at, for example, page 12, line 20 to page 13, line 1, page 7, line 18 to page 8, line 19 and page 17, lines 10-14.

New claim 40 is supported throughout the specification at, for instance, Example 9 at pages 44-46 and Example 16 at pages 59-62.

New claims 41, 42 and 45 are supported throughout the specification at, for instance, page 11, line 21 to page 12, line 19.

New claim 43 is supported by the claims.

New claim 44 is supported throughout the specification at, for instance, page 17, lines 22-25.

Reconsideration is respectfully requested.

Interview

Applicants' representative thanks the Examiner for extending the courtesy of a personal interview conducted on May 30, 2006. Proposed claim amendments were discussed at the interview and specific amendments were discussed aimed at overcoming the outstanding rejections. The arguments and amendments discussed during the interview are discussed hereinbelow.

Rejections Under 35 U.S.C. § 102(b)

Loeb et al., U.S. Patent No. 4,072,574

Claim 16 stands rejected under 35 U.S.C. § 102(b) as being anticipated by Loeb et al., U.S. Patent No. 4,072,574 (hereinafter, "Loeb et al."). (*See*, Office Action of February 21, 2006, at page 4, hereinafter, "Office Action"). Applicants traverse the rejection as set forth herein.

The Examiner states that Loeb et al. disclose a DNA synthesis reaction composition comprising an AMV DNA polymerase and a transition metal complex together with reaction components necessary for DNA synthesis.

Claim 16, as amended, recites, "A DNA synthesis reaction composition comprising: 1) a DNA polymerase; 2) water-soluble acidic macromolecular substances or water-soluble salts thereof, wherein said water-soluble acidic macromolecular substances are one or more substances selected from the group consisting of sulfated-fucose-containing polysaccharides, rhamnam sulfate, heparan sulfate, hyaluronic acid, alginic acid, polyglutamic acids, polyacrylic acids, polystyrene sulfates, and DNAs which do not serve as templates for subject DNA

synthesis or as primers; and 3) components necessary for DNA synthesis using DNA polymerase.”

Claim 16 is not anticipated by the disclosure of Loeb et al. because Loeb et al. do not disclose each and every limitation recited in claim 16. For instance, Loeb et al. do not disclose a DNA synthesis reaction composition comprising a water-soluble acidic macromolecular substance or water-soluble salt thereof, selected from the group of such substances recited in claim 16 in combination with a DNA polymerase and components necessary for DNA synthesis using DNA polymerase.

Accordingly, since Loeb et al. do not disclose the claimed water-soluble acidic macromolecular substances or water-soluble salts thereof, reconsideration and withdrawal of the anticipation rejection of claim 16 in light of Loeb et al. is respectfully requested.

Diringer et al., U.S. Patent No. 5,153,181

Claim 16 stands rejected under 35 U.S.C. § 102(b) as being anticipated by Diringer et al., U.S. Patent No. 5,153,181 (hereinafter, “Diringer et al.”). (*See*, Office Action, at page 4). Applicants traverse the rejection as set forth herein.

The Examiner states that Diringer et al. discloses a synthesis reaction comprising SR-D reverse transcriptase and any one of polyvinyl sulfates, polyvinyl phosphates and polymeric carbohydrates together with reaction components necessary to achieve DNA synthesis. However, Diringer et al. do not anticipate the presently claimed invention as recited in claim 16 because claim 16 does not recite polyvinyl sulfates, polyvinyl phosphates or polymeric carbohydrates within the group of water-soluble acidic macromolecular substances or water-

soluble salts thereof encompassed by the Markush group of claim 16 in combination with a DNA polymerase and components necessary for DNA synthesis using DNA polymerase.

The Examiner should further note that the disclosure of Diringer et al. does not encompass the DNA polymerases recited in claim 41. In addition, the Examiner should note that claim 16 does not recite dextran sulfate. Accordingly, reconsideration and withdrawal of the anticipation rejection of claim 16 in light of Diringer et al. is respectfully requested.

Filler et al., U.S. Patent No. 5,554,498

Claims 16, 31, 32 and 34 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Filler et al., U.S. Patent No. 5,554,498 (hereinafter, “Filler et al.”). (*See*, Office Action, at page 5). Claim 32 has been cancelled herein without prejudice or disclaimer, thus obviating the rejection as to claim 32. Applicants traverse the rejection as to the remaining claims as set forth herein.

The Examiner states that Filler et al. disclose a DNA synthesis reaction composition comprising a DNA polymerase and a transition metal complex. Furthermore, the Examiner states that Diringer et al. also disclose a kit for DNA synthesis comprising transition metal ion salts, DNA polymerase or reverse transcriptase, a template and a buffer solution.

However, the disclosure of Filler et al. does not anticipate the presently claimed invention as recited in claim 16 because Filler et al. do not disclose each and every limitation of the presently claimed invention. Specifically, Filler et al. do not disclose a DNA synthesis reaction composition comprising a water-soluble acidic macromolecular substance or water-soluble salt

thereof, selected from the group of such substances recited in claim 16, in combination with a DNA polymerase and components necessary for DNA synthesis using DNA polymerase.

Dependent claims 31 and 34 are not anticipated as, *inter alia*, depending from, either directly or indirectly, a non-anticipated base claim, claim 16.

Reconsideration and withdrawal of the anticipation rejection of claims 16, 31 and 34 are respectfully requested.

Rejections Under 35 U.S.C. § 103(a)

Sorge et al., U.S. Patent No. 5,556,772 and Filler et al.

Claims 18, 21, 23 and 36-38 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Sorge et al., U.S. Patent No. 5,556,772 (hereinafter “Sorge et al.”) in view of Filler et al. (*See*, Office Action, at page 6). Claims 21, 23 and 37 have been cancelled herein, thus obviating the rejection as to these claims. Applicants traverse the rejection as to the remaining claims as hereinafter set forth.

The Examiner states that Sorge et al. disclose or suggest a DNA synthesis reaction composition comprising two or more DNA polymerases, one with 3' to 5' exonuclease activity and one without that activity, other components necessary to carry out DNA synthesis and kits thereof. The Examiner further states that Sorge et al. also disclose use of thermostable DNA polymerases. Furthermore, the Examiner states that Filler et al. disclose the use of transition metal complexes in DNA synthesis reactions and kits thereof. Thus, the Examiner concludes that it would have been obvious for one of ordinary skill in the art to modify the disclosure of

Sorge et al. to include the transition metal complexes of Filler et al. to achieve the presently claimed invention.

However, neither Sorge et al. nor Filler et al. disclose a DNA synthesis reaction composition comprising a water-soluble acidic macromolecular substance or water-soluble salt thereof, selected from the group of such substances recited in claim 18, in combination with two or more kinds of DNA polymerases and components necessary for DNA synthesis using DNA polymerase. Furthermore, claim 18 recites, in part, that “the composition comprises a DNA polymerase having 3’→5’ exonuclease activity, and a DNA polymerase having no 3’→5’ exonuclease activity.” Although the Examiner states that Sorge et al. disclose a DNA synthesis reaction composition comprising such DNA polymerase activity, the reaction composition of Sorge et al. do not disclose use of water-soluble acidic macromolecular substance or water-soluble salt thereof in their reactions or kits.

Thus, since neither the disclosures of Sorge et al. nor Filler et al., either considered separately or in combination, disclose or suggest each and every limitation of the presently claimed invention, according to claim 18, the Examiner has not established a *prima facie* case of obviousness with respect to claim 18. (*See, In re Vaeck*, 947 F.2d 488, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991)).

The Examiner should further note that none of the disclosures of the cited references encompass the DNA polymerases recited in claim 45.

Claims 36 and 38 recite kits comprising the DNA synthesis reaction components of the composition of claim 18. Thus, these kits would also comprise the water-soluble acidic

macromolecular substance or water-soluble salt thereof. The kits disclosed or suggested by the disclosures of Sorge et al. and/or Filler et al. do not contain these compounds.

Reconsideration and withdrawal of the obviousness rejection of claims 18, 36 and 37 are respectfully requested.

Koster et al., U.S. Patent No. 5,928,906 and Filler et al.

Claims 18 and 22 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Koster et al., U.S. Patent No. 5,928,906 (hereinafter “Koster et al.”) in view of Filler et al. (*See*, Office Action, at page 7). Claim 22 has been cancelled herein without prejudice or disclaimer, thus obviating the rejection as to claim 22. Applicants traverse the rejection as to claim 18 as hereinafter set forth.

The Examiner states that Koster et al. disclose or suggest a composition comprising two or more kinds of DNA polymerase having 3' to 5' exonuclease activity “that is not reduced relative to wild type and Mg²⁺.” Furthermore, the Examiner states that Filler et al. disclose the use of transition metal complexes in DNA synthesis reaction compositions.

However, neither the disclosure of Koster et al. nor the disclosure of Filler et al., considered separately, or in combination, discloses or suggests a DNA synthesis reaction composition comprising a water-soluble acidic macromolecular substance or water-soluble salt thereof, selected from the group of such substances recited in claim 18, in combination with two or more kinds of DNA polymerases and components necessary for DNA synthesis using DNA polymerase.

Thus, since neither the disclosures of Koster et al. nor Filler et al., either considered separately or in combination, disclose or suggest each and every limitation of the presently claimed invention, according to claim 18, the Examiner has not established a *prima facie* case of obviousness with respect to claim 18. (*See, In re Vaeck*, 947 F.2d 488, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991)).

The Examiner should further note that none of the disclosures of the cited references encompass the DNA polymerases recited in claim 45.

Reconsideration and withdrawal of the obviousness rejection of claim 18 are respectfully requested.

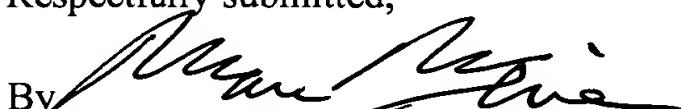
CONCLUSION

If the Examiner has any questions or comments, please contact Thomas J. Siepmann, Ph.D., Registration No 57,374 at the offices of Birch, Stewart, Kolasch & Birch, LLP.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to our Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under § 1.17; particularly, extension of time fees.

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Respectfully submitted,

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